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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,935	05/03/2001	David F. Woodward	D2914	6555

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 05/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/847,935	WOODWARD ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36,39-41,43-50,53-66,68 and 70-86* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *60-66,68,72,73,76 and 77* is/are allowed.

6)☒ Claim(s) *36,39-41,43-50,53-59,70,71,74,75 and 78-86* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02/09/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for continued examination under 37 CFR 1.114, amendment and remarks filed 02/09/2005. Claims 36, 39-41, 43-50, 53-66, 68 and 70-86 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 02/09/05 has been entered.

Information Disclosure Statement

Examiner thanks applicants for bringing to Examiner's attention prior office action in related applications. However, these references cited on the Form 1449 are not prior art references.

Claim Rejections - 35 USC § 102

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 78-86 are rejected under 35 U.S.C. 102(e) as being anticipated by Gill et al. (US 6,294,553).

Gil discloses a composition that comprises brimonidine, which is a 5-bromo-6 (2-imidazolin-2-ylamino) quinoxaline and an alpha-2-agonist (abstract, column 2, lines 50 and 61,column 3, lines 12, and 37-39), oleic acid or anionic surfactant (column 4, lines 20-22),

buffers (column 4, lines 28-37), physiological saline solution and vehicles such as poloxamers and cellulose polymers (column 4, lines 4-10); the composition of Gil is a solution or liquid applicable as an ophthalmic with a physiological saline solution as the vehicle and where the pH of the ophthalmic is between 6.5 and 7.2 (column 3, lines 65-67). Oleic acid is a fatty acid. The anionic surfactants are generally polymers. Effective amount is any amount. A pH of 7.2 is greater than 7 and lies between 7 and 9. Nothing in applicants' composition indicates that a complex would not form in the composition of the cited references. In the present case, it is a broad composition where therapeutic agent forms a complex with efficacy enhancing component. In this case the prior art teaches a composition comprising a therapeutic component and efficacy-enhancing component; and the examined claims are directed to a composition comprising a therapeutic component and efficacy enhancing component. The teaching of Gil meets the limitations of the claims.

Claim 78 is a broad teaching of a composition that comprises a therapeutic component and an efficacy-enhancing component. No amounts and/or conditions were recited that would allow the composition of the application to form a complex and exclude the same composition in the prior art from forming a complex.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claim 36, 39-41, 43, 44, 47-50, 53-59, 70, 71, 74 and 75 rejected under 35 U.S.C. 103(a) as being unpatentable over Shashoua et al. (US 5,795,909).

The generic claim is directed to a composition that comprises alpha-2-adrenergic agonist as the therapeutic agent and greater than 0.2% to about less than 10% efficacy enhancing component. The rest of the claim bears no patentable weight to the claimed invention.

Shashoua discloses a composition that contains Brimonidine tartrate (column 20, line 48), which is quinoxaline and alpha-2-adrenergic agonist, and conjugated C22 unbranched carbon chain (column 3, line 55). In this case the conjugated unbranched C22 carbon chain is cis-docosahexanoic acid. Linoleic acid and linolenic acid are all conjugated unbranched unsaturated acids that can substitute for docosahexanoic acids in pharmaceutical compositions. Thus regarding claim 46, docosahexanoic acid can be substituted for by linoleic acid with the expectation of maintaining the effectiveness of the brimonidine as quinoxaline and alpha-2-adrenergic agonist. Quinoxaline has use in the treatment of ocular conditions as an alpha-2-adrenergic agonist.

The difference between Shashoua and the instant claim is that Shashoua does not disclose amounts of the fatty acid in the pharmaceutical. However, differences in concentration/amounts will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration/amount is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Secondly, there is no demonstration in applicants' specification showing that efficacy enhancing component in amounts greater than 0.2% and less than 10% provides unusual results. Also, since Shashoua is silent on the amount of the efficacy-enhancing component, it would appear that all or certain amount of the efficacy enhancing component would be suitable to

provide the desired effect and it is within the purview of the person of skill or of ordinary skill to determine the workable amount of the efficacy enhancing component. The burden is on applicants to demonstrate such is the case. There is no demonstration that a complex will not form in a medium where the quinoxaline and the fatty acid are present. There is no demonstration that complex formation is excluded outside of the range of 0.2% (w/v) to less than 10% (w/v).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the composition of Shashoua that comprises a therapeutic agent and a conjugated unsaturated fatty acid. One having ordinary skill in the art would have been motivated to optimize the composition of Shashoua by including appropriate amount of the conjugated unsaturated fatty acid and therapeutic agents in a composition that would be expected to effectively treat mammalian cell proliferative disorder.

6. Olejnik et al. (US 6,627,210) renders obvious claims 36, 39-41, 43, 44, 47-50, 53-59, 70, 71 and 74 as Shashoua. See claims 1-34.

7. Claims 36, 39, 45-50 and 53-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanssler et al. (Derwent Database on West, DE 3309765).

Hanssler (English abstract) discloses a composition comprising quinoxaline and vegetable oil or linoleic acid and lecithin. Claim 36 is a therapeutic composition and ion pair complex would inherently form when the quinoxaline and linoleic acid are present in a mixture except there is evidence to the contrary that such a complex would not form.

The difference between Hanssler and the instant claim is that Hanssler does not disclose amounts of the fatty acid in the pharmaceutical. However, differences in concentration/amounts

will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration/amount is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Secondly, there is no demonstration in applicants' specification showing that efficacy-enhancing component in amounts greater than 0.2% and less than 10% provides unusual results. Also, since Shashoua is silent on the amount of the efficacy-enhancing component, it would appear that all or certain amount of the efficacy-enhancing component would be suitable to provide the desired effect and it is within the purview of the person of skill or of ordinary skill to determine the workable amount of the efficacy-enhancing component. The burden is on applicants to demonstrate such is the case. There is no demonstration that a complex will not form in a medium where the quinoxaline and the fatty acid are present. There is no demonstration that complex formation is excluded outside of the range of 0.2% (w/v) to less than 10% (w/v). Regarding docosahexanoic acid, one fatty acid can be substituted for the other without loss of effect of the quinoxaline. Quinoxaline has use in the treatment of ocular conditions as an alpha-2-adrenergic agonist.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the composition of Hanssler that comprises a quinoxaline, linoleic acid and lecithin. One having ordinary skill in the art would have been motivated to optimize the composition of Hanssler by including appropriate amount of the fatty acid and quinoxaline in a composition that would be expected to effectively treat fungus disease.

Claims 60-66, 68, 72, 73, 76 and 77 are allowable because the prior art does not disclose ion-pair that includes therapeutic agent that is alpha-2-adrenergic agonist and efficacy enhancing component that is anionic polymer or fatty acid.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
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